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ISPAD GUIDELINES

ISPAD Clinical Practice Consensus Guidelines 2022: Diabetes technologies: Glucose monitoring

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SUMMARY OF WHAT IS NEW OR DIFFERENT

Since publication of the 2018 guidelines, the area of glucose monitoring has evolved, especially as regards continuous glucose monitoring (CGM) systems. CGM is more widely available in many parts of the world; latest generation devices are factory-calibrated, more accurate, and do not need a confirmatory fingerstick blood glucose measurement. More studies regarding the efficacy of CGM systems, irrespective of the type of insulin delivery, are available including long-term observational studies. With increased availability and wider use, practical considerations related to daily CGM use (e.g., skin issues, physical activity) as well as educational and psychosocial aspects have come to the fore, which are also addressed in this chapter.

[Correction added on 24 January 2023, after first online publication: The name of the eleventh author was corrected in this version.]

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EXECUTIVE SUMMARY AND RECOMMENDATIONS

- Regular self-monitoring of glucose (using accurate fingerstick blood glucose [BG] measurements, real-time continuous glucose monitoring [rtCGM] or intermittently scanned CGM [isCGM]), is essential for diabetes management for all children and adolescents with diabetes. **A**
  - Each child should have access to technology and materials for self-monitoring of glucose levels and sufficient supplies to optimize diabetes care. **B**
  - When fingerstick BGs are used, testing may need to be performed 6 to 10 times per day to optimize glycemia. **B**
  - Frequency of BG testing correlates with improved HbA1c levels and reduced acute complications. **B**
  - Regular review of glucose values should be performed to inform adjustments to medication/nutritional therapies to optimize glycemia. **B**
  - Diabetes center personnel should advocate to nations, states, and health care funders to ensure that children and adolescents with diabetes have adequate glucose monitoring supplies. **E**
- Providers should be aware of the differences in accuracy among BG meters—only meters that achieve international accuracy standards (ISO 15197:2013 or are FDA-approved) should be used. **E**
- Use of CGM is strongly recommended in all children, adolescents, and young adults with type 1 diabetes (T1D). **A**
- Where available, CGM should be initiated in all children, adolescents, and young adults with T1D as soon as possible after diagnosis to improve glycemic outcomes. **B**
- isCGM, also known as flash glucose monitoring, in the pediatric population is safe, may improve time in range (TIR) and HbA1c levels, decreases time in hypoglycemia, and lowers glycemic variability. **B**
- For isCGM, higher scanning frequency (11–13 scans/per day) is associated with more favorable glycemic markers (HbA1c and TIR). **B**
- rtCGM can be effectively used to lower HbA1c levels, reach target HbA1c level, reduce glucose variability (for insulin pumps, closed-loop systems, and multiple daily injections [MDI]), increase TIR, reduce mild to moderate hypoglycemia and shorten time spent in hypoglycemia in the pediatric population with T1D. **A**
- rtCGM data can particularly benefit children who cannot articulate symptoms of hypoglycemia or hyperglycemia and those with hypoglycemic unawareness. **A**
- The effectiveness of rtCGM in children and adolescents with T1D is related to the amount of time the sensor is used. **A**
- Prior to CGM start, portray the use of diabetes devices and technologies as an option that can be a good fit for many youth and families; provide education and encourage youth and families to review vetted websites and device informational materials. **E**
- Structured initial and ongoing education and training in CGM use (including data review) is paramount to successful adoption and continued use of this technology. **E**

TABLE 1 Comparison of ISO 15197:2013 and FDA BG meter accuracy standards

Setting	ISO 15197:2013[5]	FDA[6,7]
Home use	95% within 15% for BG ≥100 mg/dl 95% within 15 mg/dl for BG <100 mg/dl 99% in A or B region of consensus error grid[a]	95% within 15% for all BG in the usable BG range[b] 99% within 20% for all BG in the usable BG range[b]
Hospital use		95% within 12% for BG ≥75 mg/dl 95% within 12 mg/dl for BG <75 mg/dl 98% within 15% for BG ≥75 mg/dl 98% within 15 mg/dl for BG <75 mg/dl

Abbreviations: BG, blood glucose; FDA, U.S. Food and Drug Administration; ISO, International Organization for Standardization.
[a]The range of blood glucose values for which the meter has been proven accurate and will provide readings (other than low, high, or error).
[b]Values outside of the "clinically acceptable" A and B regions are considered "outlier" readings and may be dangerous to use for therapeutic decisions.[8]

- Setting realistic expectations for the integration of diabetes technologies is paramount to ensure the success of persons and caregivers adopting new technologies. **B**
- It is critical to counsel youth/families and identify potential barriers to adoption of new technologies or continued use of devices. Validated person-reported outcome measures can help to identify barriers. **B**

1 | INTRODUCTION

Self-monitoring of glucose has a pivotal role in the management of insulin-treated children and adolescents with diabetes. It tracks immediate and daily glucose levels including periods of hypo- and hyperglycemia, helps guide insulin dose adjustments, facilitates evaluation of therapy responses and achievement of glycemic targets in a safe and effective manner.

Along with major clinical trials demonstrating the superiority of intensive insulin therapy in persons with T1D in the early 1990s,[1] self-monitoring of capillary blood glucose (SMBG) using hand-held portable meters in combination with glucose test strips and a lancet became the most widely used method of glucose monitoring, replacing urine glucose testing.

In recent years, systems for continuously monitoring interstitial fluid glucose concentrations, CGM, using subcutaneously placed glucose sensors have become standard of care in T1D in many countries, particularly for children, adolescents, and young adults,[2] and have been successfully employed for insulin-treated type 2 diabetes.[3]

The purpose of this chapter is to review and update the evidence on glucose monitoring devices (i.e., SMBG and CGM) in children, adolescents, and young adults and to provide practical advice and approaches to their use.

TABLE 2 Factors that alter BG measurements

Glucose oxidase monitors	
Substances that decrease readings	*High ambient oxygen*
	Uric acid
	Acetaminophen
Substances that increase readings:	*Low ambient oxygen*
Substances with variable effect:	*L-DOPA*
	Ascorbic acid
	Tolazamide
Glucose dehydrogenase monitors	
Substances that increase readings:	*Galactose*
	Xylose

Abbreviation: BG, blood glucose.

2 | SELF-MONITORING OF CAPILLARY BLOOD GLUCOSE

Early SMBG measurement methods relied upon reflectance assays coupled with oxidation of glucose allowing for a colorimetric readout. Currently available glucose meters use an electrochemical method with an enzyme electrode containing either glucose oxidase or glucose dehydrogenase.

2.1 | Meter standards and accuracy

There is considerable variation in the accuracy of widely-used BG monitors.[4] Most reliable data are provided by meters meeting current international accuracy standards. The two most used standards are those of the International Organization for Standardization (ISO) (ISO 15197:2013) and the U.S. Food and Drug Administration (FDA) (Table 1). ISPAD recommends exclusive use of glucose meters that achieve these standards. Health care professionals should choose and advise on meters that are accurate and familiar to them as well as affordable to the person with diabetes.

The specified accuracy standard achieved during controlled conditions might vary significantly from actual SMBG meter performance in real-world settings.[4] Detailed information on the actual performance of SMBG devices is provided by The Diabetes Technology Society Blood Glucose Monitoring System Surveillance Program (www.diabetestechnology.org/surveillance/).

SMBG accuracy depends on proper hand washing with complete drying[9] and requires proper blood application and use of adequately stored, unexpired test strips, which are not counterfeit nor preowned/second hand.[10] Providers and persons with diabetes/caregivers need to be aware of additional factors that can impair meter accuracy: Due to the enzymatic electrochemical reaction, monitors are sensitive to temperature and have a defined operating temperature range.[10] Typically, an error message is displayed if the temperature is out of range. Unlike glucose dehydrogenase-based meters, glucose oxidase meters are sensitive to the ambient oxygen and should only be used with capillary blood of people with normal oxygen saturation. Low oxygen tensions (i.e., high altitude, hypoxia, venous blood readings) may result in falsely high glucose readings, higher oxygen tensions (i.e., arterial blood) may lead to falsely low readings.[10] There are also several substances that may interfere with glucose readings (Table 2).[10]

2.2 | Expert meters

Expert BG meters have integrated bolus advisors to calculate insulin dosages. Randomized controlled trials (RCTs) have shown use of a bolus calculator significantly increases the number of people achieving HbA1c targets and reduces hypoglycemia.[11–13]

2.3 | Frequency and timing of SMBG testing

SMBG frequency correlates with improved HbA1c levels and reduced acute complications.[14–16] Generally, SMBG should be performed at a frequency to optimize each child's diabetes. For persons using intensive insulin regimens (multiple daily injections of insulin pump therapy), SMBG testing should be performed:

- during the day, prior to meals and snacks,
- at other times (e.g., 2–3 h after food intake) to determine appropriate meal insulin doses and show levels of BG in response to the action profiles of insulin (at anticipated peaks and troughs of insulin action)
- to confirm hypoglycemia and after treating low BG to monitor recovery
- at bedtime, as needed overnight and on awakening to detect and prevent nocturnal hypoglycemia and hyperglycemia
- prior to and while performing potentially hazardous tasks (e.g., driving)
- In association with vigorous exercise (before, during, and several hours after physical activity)
- during intercurrent illness to prevent hyperglycemic crisis.

Successful intensive insulin management requires at least 6 to 10 checks per day, appropriate response to the observed values, and regular, frequent review of the results to identify patterns requiring adjustment to the diabetes treatment plan.[15] This includes review by the person with diabetes and their caregivers/family in addition to consultation with the diabetes care team.

However, the actual number and regularity of fingerstick BG measurements should be individualized depending on:

- type of insulin regimen
- ability of the child to identify hypoglycemia
- availability and affordability of meters and test strips

In resource-limited settings, availability and affordability of glucose meters and test strips are not guaranteed. Even though many

children are on multiple daily injection regimens, only a few can afford frequent BG testing needed to optimize diabetes management. Very often testing is performed 3–4 times a day (i.e., pre-breakfast, pre-lunch, pre-dinner, and at bedtime). However, many persons with diabetes must resort to two times daily, that is, before breakfast and before dinner. If there are no BG monitoring capabilities, then urine testing is performed. For a comprehensive discussion on aspects of diabetes management in resource-limited settings, including glucose monitoring, please refer to the ISPAD 2022 Consensus guidelines Chapter 25 on 'Management of Diabetes in Children and Adolescents in Limited Resource Settings.

3 | CONTINUOUS GLUCOSE MONITORING

Rapid, capillary assessments of BG concentrations have been instrumental in permitting achievement of recommended targets over the past 30 years. However, SMBG only provides single snapshots of glucose concentrations. Consequently, episodes of hyper- and hypoglycemia, in particular nocturnal and asymptomatic episodes, as well as considerable fluctuations in BG concentrations may be missed and therefore not factored into treatment decisions.

The emergence of CGM in the late 1990s represented a significant therapeutic milestone. Instead of single-point measurements of capillary blood glucose concentrations, CGM devices measure interstitial glucose concentrations subcutaneously at 1–15 min intervals using enzyme-coated electrodes or fluorescence technology. Significant improvements in device technology over the past decade (including improved accuracy, approval for non-adjunctive use, and reduced need for calibration), availability, smaller size, remote monitoring capability, and overall personal acceptance of CGM systems have contributed to the widespread adoption of this technology in clinical practice.

3.1 | CGM use and uptake

In many countries, CGM use has now become the standard of care for people with T1D.[2] According to data from German and Austrian DPV and U.S. T1D Exchange registries, CGM use increased exponentially from 2011 to 2017 in all pediatric age-groups (DPV: 4% in 2015 to 44% in 2017; T1DX: 4% in 2013 to 14% in 2015 and to 31% in 2017), with the highest use among preschool-aged and early school-aged children.[17] From 2017 to 2020, further increase in CGM use among individuals with diabetes aged <25 years was seen in both registries each year for all age ranges (DPV: 40% in 2017 to 76% in 2020; T1DX: 25% in 2017 to 49% in 2020).[18] Recent data from the Australasian Diabetes Database Network (ADDN) registry and the Australian National Diabetes Service Scheme (NDSS) demonstrate 79% of registry participants with T1D aged <21 years are using CGM.[19]

DPV and T1D Exchange registry data indicate significant disparities in CGM use by socioeconomic status (SES). Of note, in the T1D Exchange registry, the gap of device use between highest and lowest SES quintiles (52.3% vs. 15.0%) was more pronounced than in the DPV population (57.1% vs. 48.5%).[20] Adequate clinic-specific resources and interventions to identify and overcome barriers to CGM uptake are necessary to promote CGM adoption and continued use.[21] In a multiclinic quality improvement initiative of the T1D Exchange Quality Improvement Collaborative, center-specific interventions consisting of active person support and education, training and education of the clinical team, as well as interaction with insurance companies and vendors led to increases in CGM use from 34% to 55% in adolescents and young adults over 19–22 months.[21]

3.2 | Categories of sensors

CGM systems fall into one of the following categories:

1. Blinded CGM or professional CGM;
2. Real-time CGM;
3. Intermittently scanned CGM (isCGM) or Flash CGM;

Blinded/retrospective/professional CGM

Blinded or professional CGMs were the first widely used CGM devices, for example, the MiniMed CGMS Gold system (Medtronic MiniMed, Northridge, CA) released by Medtronic in 1999. Professional CGM systems obtain short-term glucose data which are not visible to the user. They provide health care professionals with data showing glucose excursions and patterns. In addition to clinical practice, professional CGM systems are sometimes employed in research settings to obtain retrospective glucose data and to reduce potential bias (e.g., in certain settings people may deviate from their usual behavior when seeing their CGM readings in real-time).

Real-time CGM

Real-time CGM (rtCGM) systems automatically display glucose values at regular intervals and can utilize programmable alarms when sensor glucose levels reach predefined hypo- or hyperglycemia thresholds, as well as rate-of-change alarms for rapid glycemic excursions. Many commercially available rtCGM systems transmit glucose data directly to smartphones. These data can then be stored and retrieved on a web server ("cloud") and used for remote monitoring purposes by caregivers and healthcare professionals.

In addition to traditional, self-inserted transdermal sensors with a lifetime from 6 to 14 days, a long-term implantable sensor for up to 6-month use is available (Eversense, Senseonics Inc., Germantown, MD) that received regulatory approval in the European Union (Conformitè Europëenne [CE] Mark) in 2016 and subsequently in other regions. Of note, the Eversense CGM is currently approved only for use in adults over 18 years of age. Its implantation requires a minor in-clinic procedure performed by a trained physician or a nurse practitioner. Unlike traditional CGM sensors, where glucose is measured using the enzyme-based electrochemical method, the Eversense implantable sensor uses non-enzymatic optical fluorescence. The next-generation Eversense CGM has 180-day long-term wear time with daily calibration.[22]

Intermittently scanned CGM

In 2014, the FreeStyle Libre Flash Glucose Monitoring System (FSL) (Abbott Diabetes Care, Alameda, CA) was introduced representing a different CGM category: intermittently scanned CGM (isCGM). IsCGM devices do not automatically display glucose values at regular intervals, but report glucose levels only when the user scans the sensor by holding a reader, or a near field communication protocol (NFC)-enabled smartphone, close to or over the sensor. Current interstitial glucose levels and glucose trend arrows as well as a graph of current and stored glucose readings are provided on demand.[23] As with rtCGM, glucose data from isCGM can be transferred from a smartphone to a webserver for remote glucose monitoring purposes by caregivers or health care professionals. The sensor can provide glucose values up to 14 days after a 1-h sensor warm-up period.

The second generation of FreeStyle Libre (FSL2) was approved in Europe in 2018 and in the USA in 2020. FSL2 sensors have higher accuracy (mean absolute relative difference [MARD] 9.2% and 9.7% for adults and children,[24] respectively) and, in addition to the general FSL capabilities, have optional alarms to alert persons in case the glucose level is out of the target range. To see the actual level, the user must scan the sensor. The third generation, the FSL3, is actually a rtCGM providing real-time alarms and real-time readings without the need to scan. It received CE marking in 2020.

3.3 | Accuracy of CGM devices

The accuracy and precision of first generation CGM systems were notably inferior to those of capillary BG monitors. Over the past 10 years, however, there has been continued improvement in the accuracy. Discrepancies between actual BG and CGM levels, however, continue to occur in the hypoglycemic range and when glucose levels are changing rapidly. To a great extent this is due to the physiological delay of about 5–10 min between the flow of glucose from the intravascular to interstitial compartments.[25] Accuracy is also influenced by the time it takes for the sensor to react to glucose[26] and the use of digital filters for smoothening of the sensor signal during conversion of the measured sensor signal into a glucose value.[26,27] Sensor performance also may be affected by biomechanical factors such as motion and pressure (typically micro-motion and micro-pressure).[28]

Methods used to assess the accuracy of CGM systems include the mean absolute relative difference (MARD) between sensor readings and reference BG values (absolute difference divided by the reference value, expressed as percentage) and error grid analysis. MARD is currently the most common metric used to assess the performance of CGM systems. Of note, MARD has its limitations, and its use as the sole performance parameter for CGM systems must be viewed critically.[29] The lower the MARD, the closer CGM readings are to the reference glucose values. Error Grid analysis allows one to assess clinical significance of the discrepancy between the sensor and the reference glucose measurement; greater accuracy corresponds to a higher percentage of results in Zone A and B. Accuracy continues to improve with each new generation of CGM sensors and systems. For most commercially available CGM systems, the accuracy in clinical trials reached 8%–10% MARD with about 99% of glucose readings within the clinically acceptable error Zones A and B.[24,30,31] It should be noted that in the home-use setting CGM system may produce higher average MARDs than during in-clinic studies.[32]

Unlike BG meters (see Table 1), for CGM, the minimum accuracy requirements have not been determined until recently, and there are no consistent standards in the approval of CGM systems, particularly in relation to the provision of clinical data demonstrating the device's accuracy in the intended use population, as well as transparency and access to this data. Recently, the FDA has outlined a new 510 K (premarket approval) route for some CGM systems, designated as "integrated CGM" (iCGM) with additional special controls governing accuracy ability of this device to work with different types of compatible diabetes management devices, including automatic insulin dosing systems, insulin pumps, and BG meters.[33]

3.4 | Sensor interference

Certain exogenous and endogenous interstitial fluid substances, including some commonly-used medications, may interfere with CGM system accuracy. This can result in falsely high or low glucose values.

In particular, therapeutic doses of hydroxyurea can markedly elevate sensor glucose readings compared with glucose meter values[34]; likewise, acetaminophen at a dose of 1000 mg can falsely elevate sensor glucose values in certain CGM systems.[35,36] Salicylic acid at doses ≥650 mg may mildly reduce glucose readings, and ascorbic acid (vitamin C) at doses ≥500 mg may cause falsely higher readings.[37] CGM readings may also be affected by ingestion of lisinopril, albuterol, atenolol, and red wine.[38]

The effect of different substances on glucose reading depends on sensor technology. Specifically, CGM systems that use enzymatic electrochemical sensors to measure glucose concentrations seem to be more susceptible to interference than systems using abiotic (non-enzyme based), fluorescent glucose-indicating polymer to measure glucose. In particular, for the long-term implantable fluorescence-based sensor only tetracycline and mannitol produced significant sensor bias when tested in vitro within therapeutic concentration ranges.[39]

Medications such as salicylic acid, acetaminophen and vitamin C, commonly available over the counter for self-administration, and may be present in combination products or supplement formulations leading to persons with diabetes not knowing that they are taking specific substances. Sensor bias produced from various substances can be most significant for persons using CGM data without confirmatory measurements of capillary BG or for those using CGM data to inform insulin delivery in closed-loop systems. Therefore, CGM users should be aware of how certain systems may be impacted by common medications and always test with a glucose meter whenever symptoms do not match a CGM reading.

3.5 | Calibrations/factory-calibrated systems

The latest generations of rtCGM systems (i.e., Dexcom G6, Dexcom G7, Guardian 4) and all available isCGM (FSL1, FSL2) are factory-calibrated, meaning that user calibrations using fingerprick glucose measurements are generally not needed. This eliminates pain and inconvenience and takes away a significant source of error from sensor calibration. Factory calibration is performed under laboratory conditions during the sensor manufacturing process.[40] For rtCGM manual calibration is still possible, for example, if CGM readings and results from capillary BG readings do not line up well over a prolonged period of time.

For older generation CGM sensors that depend on manual calibrations (i.e., entering BG readings from a meter into the CGM system), the required calibration frequency varies by device. Typically, the first calibration is performed 1–2 h after insertion of the sensor and thereafter a minimum of one calibration is required every 12 h. For these systems, regular calibrations are essential to maintain the accuracy and optimum sensor performance. The optimum times to calibrate are when the interstitial fluid glucose concentration is in equilibrium with the capillary blood, i.e. when glucose levels are least likely to be changing rapidly: before meals, before bedtime, before insulin administration, when trend arrows on the CGM/pump screen show glucose levels are stable. User calibration can lead to wrong sensor reading if at the time of calibration the sensor signal has a temporarily falsely reduced or elevated value, for example, caused by interfering substances or site compression ("compression lows").[40]

3.6 | Non-adjuvant use

RtCGM systems were originally approved for adjunctive use, meaning the sensor glucose results needed to be verified by capillary SMBG before taking action (e.g., insulin dosing). Along with significant improvements in accuracy, more and more sensors have received approval for non-adjuvant use, that is, diabetes-related decisions and insulin dosing are made based on CGM values alone.

Studies utilizing computer modeling have shown that the threshold MARD level of ≤10% is safe for non-adjuvant use of CGM[41] and most currently-available commercial CGM systems meet this condition. Furthermore, the T1D Exchange REPLACE BG study provided evidence of the safety and effectiveness of non-adjunctive sensor use.[42]

Dexcom sensors (G5 and G6™ Mobile CGM, Dexcom, San Diego, CA) have received FDA and CE approval for non-adjunctive use in persons aged 2 years and older. The Abbot Libre Flash Glucose Monitors (Abbott Diabetes Care, Alameda, CA) have received FDA and CE approval for treatment decisions in persons aged 4 and older. The Medtronic Guardian 4 sensor is CE marked for nonadjunctive use from the age of 7 years. Fingerprick testing may still be recommended under certain circumstances: hypoglycemia, if glucose is changing rapidly, and especially if symptoms are not concordant with the system readings.

Efficacy of CGM

Real-time CGM systems

Early-generation rtCGM systems use for children with T1D was associated with only modest benefits in glycemia when compared with SMBG.[43–45] The 2008 JDRF landmark randomized clinical trial (RCT)[46] showed no overall glycemia benefit with CGM use in the younger age groups (8–14 years and 14–25 years), likely related to <50% sensor wear usage in these groups. A secondary analysis demonstrated benefits across all age groups when the sensor was used ≥6 days/week.[47] RCTs and meta-analyses conducted since 2010 utilizing newer generation rtCGM systems more consistently show that use of rtCGM is able to improve glycemia in both children and adults with T1D and, depending on the population studied, benefits are seen in terms of lower HbA1c concentrations, increased TIR, reduced hypoglycemia (including severe hypoglycemia), and reduced glucose variability.[3,43,48–52] There is now emerging evidence that improvement in glycemia is equivalent in users of insulin pump therapy and MDI therapy.[50,53–57]

Contemporary large registry-based studies have shown that compared to SMBG, use of rtCGM is associated with lower HbA1c levels, a higher proportion of people achieving ISPAD HbA1c targets, and fewer episodes of DKA in children and adolescents.[2,17,58–63] This positive effect on HbA1c has also been seen in a Swedish registry-based study that described a progressive decrease of HbA1c in very young children during the 2008–2018 period, in parallel with the increasing use of pumps and CGM.[64] Data from national population-based registries following rtCGM/isCGM reimbursement programs report improvement of T1D glycemic outcomes in children, adolescents, and adults.[65–67]

In contrast, registry-based studies have not consistently shown a lower number of severe hypoglycemic events in people using rtCGM.[2,60–62] Tauschmann et al. analyzed real world data from people with T1D aged <18 years from Germany, Austria, and Luxemburg in the DPV Registry and showed a reduction in severe hypoglycemic events during the first year of CGM use.[59] Interestingly, data from observational studies in children and adolescents, suggest that, irrespective of insulin delivery system, early initiation of CGM within 1 year of T1D diagnosis is associated with fewer severe hypoglycemic events and more favorable glucose outcomes.[68,69]

RCTs using the latest-generation non-adjunctive rtCGM systems have shown positive effects on both HbA1c levels and TIR[70,71] in adolescents and young adults. The MILLENIAL Study of a factory-calibrated rtCGM showed that TIR increased when compared with SMBG.[71] Supporting this finding, data from single-center observational studies with selected population aged <20 years have reported a decrease of HbA1c levels after initiation and with uninterrupted use of rtCGM.[68,72]

Data from RCTs in young children have replicated the results of studies from adolescents and young adults. Though data from small observational studies suggest that CGM can be used successfully in children <8 years,[73–75] a more recent trial of non-adjunctive rtCGM in 143 very young children (mean age 5.7 years) did not show a statistically significant improvement in TIR. However there was a substantial reduction in the rate of hypoglycemia seen with rtCGM vs traditional

capillary BG measurements over 6 months.[76] Using data from the Slovenian National Registry, Dovc et al demonstrated that the use of CGM was well tolerated by pre-school children and that a positive effect was observed in glucose variability.[75]

isCGM systems

To date very few RCTs have been conducted using isCGM,[55,77] and only one in adolescents and young adults.[77] The IMPACT multicenter isCGM RCT focused on ameliorating hypoglycemia and involved adults with HbA1c <7.5% at study entry. It demonstrated that isCGM use reduced time spent in hypoglycemia, reduced glucose variability, and improved TIR (3.9 to 10.0 mmol/L, 70 to 180 mg/dl) when compared to SMBG.[55] Similar results, including significantly reduced time in hypoglycemia without deterioration of HbA1c were observed in a subgroup analysis of the IMPACT RCT in adults with T1D managed with MDI therapy.[78] However, the effect of this technology in those with suboptimal glycemia remains less certain. In a 6-month RCT in youth aged 13 to 20 years with elevated HbA1c (HbA1c ≥ 9%), Boucher et al did not demonstrate differences in HbA1c levels when using isCGM compared to SMBG.[77] Nevertheless, this youth population increased testing frequency 2.5 fold and reported a higher satisfaction with its treatment.[79]

Data from observational clinical studies in children aged 4–18 years at isCGM initiation have shown greater TIR[80] and lower HbA1c[80,81] compared to SMBG use prior to isCGM start,[80,81] similar to what has been described in adults.[82–84] Interestingly, when comparing isCGM users across different age groups,[85,86] benefits were more pronounced in children under 12 years[85] and preschool children[86] compared to adolescents[85,86] and adults.[85] Scanning frequency (11–13 scans/per day) is associated with favorable glycemic markers (HbA1c and TIR) though not with reduction of time in hypoglycemia.[80,81,85,87,88] These studies were all performed using first-generation systems without alarms for impending hypo- and hyperglycemia. Studies using newer systems with optional real time alarms and improved accuracy are needed.

In addition, anonymized real-world data studies have also shown increased scanning frequency benefits time in hypoglycemia.[67,89,90] One observational study in children and adults using data from 12,256 individuals in the Scotland national diabetes registry found that isCGM initiation was associated with significant reductions in HbA1c with the greatest reductions in those with highest starting HbA1c values and children <13 years of age; DKA episodes were also decreased except in adolescents; among those at higher risk for severe hypoglycemia requiring hospitalization (SHH), a marked reduction in SHH event rates was also observed.[91] A prospective real-world cohort study after 1 year of nationwide reimbursement of isCGM in Belgium reported fewer severe hypoglycemia and DKA events with the use of isCGM.[66]

Rt CGM versus isCGM

In recent years, studies directly comparing rtCGM and isCGM systems have been published, including observational studies in children and adolescents[92] and adults with T1D,[93] and one RCT in adults.[94] All showed superiority of rtCGM over isCGM in terms of improved TIR and reduced percentage of time in hypoglycemia. However, the number of studies and the number of trial participants were limited, particularly in children and adolescents. Additionally, mainly older generation devices were used.

TABLE 3 Basic guidelines for starting CGM use

Before initiation • Review device components and features • Advocate for insurance coverage/reimbursement • Support consistent options for CGM supply provision • Provide access to customer service contact for technological support • Ensure/arrange access to CGM data platforms

Device insertion and adherence
• Review sensor site selection, site rotation, signs, and symptoms of cutaneous/subcutaneous issues
• Review insertion techniques
• Offer supplementary adhesive products. These include:
  ○ Wipes: Skin tac IV prep, skin prep
  ○ Dressings and barriers: Tegaderm, IV-3000, Hypafix
  ○ External Wraps: Coban, Pre-Wrap
• Offer adjunctive adhesive removers, such as Unisolve or Detachol, or products one may have at home, like baby oil
• Review signs/symptoms of skin irritation/contact dermatitis

Calibration
• For sensors requiring calibrations, discuss frequency of calibrations and ideal times to calibrate
  ○ Consider pre-emptive calibration schedule. If calibrations are required every 12 h, encourage persons to calibrate three times a day (for example, prior to breakfast, dinner and bedtime)
  ○ Discuss calibrating when glucose is relatively stable (arrow shows glucose stable, no rapid change on sensor glucose graph)

Alerts and alarms
• Consider leaving alerts off initially to help avoid alarm fatigue.
• When incorporating alerts, personalize them and use wide thresholds at first (i.e. 70-250 mg/dL [3.9–13.9 mmol/L]). These can be adjusted over time.
  ○ For those with recurrent hypoglycemia, set low alert first.
  ○ For those with sub-optimal glycemia, consider setting high alert first.
• In the beginning, do not employ rate of change or predictive alerts. Consider how these additional alerts may be actionable moments prior to incorporating them. This will help prevent alarm fatigue.
• Rate of change alerts or predictive alerts might be turned on in situations where rapid changes in glucose levels are more likely than under normal everyday conditions (e.g. more physical activity, eating different types of foods).

Retrospective Review • Encourage downloading, if required, to review data • Encourage retrospective data review to inform insulin dose titrations
Real-time data • As appropriate discuss non-adjunctive use of sensor data • Review significance of sensor lag • Review significance of trend arrows • Consider recommendations on adjustments of insulin doses based on sensor glucose values and trend arrows[111,112]

CGM use from diabetes onset

Tight glycemia from diabetes onset has been shown to benefit long-term glycemic trajectories in individuals with T1D.[95] Early introduction of CGM among children with new onset diabetes was

associated with a 0.66% lower HbA1c at 12 months after diagnosis compared to those who did not start CGM.[68] Long-term improvement in HbA1c over a 7-year follow up period was seen when CGM was initiated in the first year after T1D diagnosis compared to no CGM use or when CGM initiation after the first year.[96]

Residual beta-cell preservation, often assessed by residual C-peptide secretion, has long been a goal of interventions for persons with new onset T1D to decrease risk of long-term diabetes related complications.[97–99] There are several ongoing studies investigating the benefit of more modern factory-calibrated CGM and hybrid closed loop systems in preserving beta-cell function in the new onset period. As the role of CGM and CGM-derived metrics in clinical trials as outcome parameters is being established,[100] CGM will be used increasingly to monitor glycemic trajectories in pharmacologic intervention studies on diabetes onset or prevention. There will also be a role for CGM in the monitoring of people at high risk of developing T1D following positive islet antibody screening.[101,102]

Practical considerations

Education

Initial and ongoing education and training in CGM use remains a keystone to optimizing CGM uptake and long-term use, as glycemic benefits are only observed if the device is worn consistently.[103] While many aspects of CGM use remain largely intuitive,[104] structured training of youth and parents/caregivers about CGM device components, insertion, skin care, and data interpretation is critical to assure safe and effective use of this technology.[103,105] Further, ongoing education and support are recognized as essential to overcome barriers to consistent CGM use and as technologies are continuously updated.[103,106] Follow-up training is also recommended to teach users how to analyze and interpret their glucose data.[107,108] In addition, psycho-educational support is helpful to set realistic expectations and to address individual education and training needs.[103]

Structured educational material and written healthcare plans to support CGM use should also be provided to caregivers of children with diabetes, including daycare providers, school nurses, teachers, babysitters, after-school program supervisors.[103,109,110] Table 2 provides an overview of the structured education aspects to consider at CGM initiation (Table 3).

Exercise

CGMs can be helpful in reducing glycemic excursions associated with exercise, which represent a challenge for youth and their parents/caregivers.[113] RtCGM has proven to be effective in both the prevention and early detection of exercise-induced hypoglycemia.[114]

Limited data exist on the efficacy of isCGM in maintaining optimal glycemia during exercise when compared to rtCGM. In a RCT in adults with T1D, the use of rtCGM was superior to isCGM in reducing hypoglycemia and improving TIR during exercise.[94]

The use of predictive hypoglycemia thresholds and rate-of-change in glucose alerts in rtCGM devices, allows prompt action to avoid glycemic fluctuations during and after exercise.[94,115,116] Also, the use of thresholds for lower glucose values allows the user to consider carbohydrate consumption with respect to the rate-of-change in glucose and the trend arrows.[115–118]

A recent position statement recommends different glycemic ranges before, during and after exercise according to the age group, the type of exercise, the risk for hypoglycemia and in accordance with the trend arrows.[117] However, these recommendations represent a general approach that needs to be personalized for the individual child and parents/caregivers.

CGM remote monitoring tools also offer the possibility for parents/caregivers to facilitate supportive action in case of glycemic excursions associated with exercise[118] or to avoid post-exercise nocturnal hypoglycemia in children.[119]

For more information on exercise in children and adolescents with diabetes, please refer to the ISPAD 2022 Consensus Guidelines Chapter 14 on Exercise in children and adolescents with diabetes.

CGM and skin issues

Inflammatory skin reactions elicited by non-specific skin irritation or delayed-type allergy to adhesive or device materials remain a barrier to consistent long-term CGM use, especially in young children.[120] Rate of cutaneous complications from CGM use in clinical trials were comparably low with one event per 8 weeks of sensor wear-time.[121] However, there appear to be discrepancies between trial reporting and observational data.[121] Reports on skin issues related to CGM use are becoming more frequent with the long-term use of sensors and the availability of devices with longer wear time.[122,123] CGM-associated skin conditions include localized eczematous reactions under the device or the fixation plasters, post inflammatory hyperpigmentation at CGM sensor insertion sites, device-associated pruritus at the application site.[124,125] Increasing evidence identifies sensitizing components of sensors and adhesives as factors possibly responsible for skin reactions, including allergic contact dermatitis.[126,127] The exact adhesive composition is rarely made available by manufacturers, but most devices contain acrylate, which can cause contact dermatitis.[127] Recently, initiatives for full and accurate labeling of the chemical composition of devices were presented.[128] Strategies to preserve skin integrity include correct device placement, prophylactic skin care, proper removal techniques, and promotion of skin healing. In addition, barrier agents to minimize the risk of hypersensitivity reactions may reduce the risk of skin irritation due to frequent sensor use.[129]

For more information on skin related issues, please refer to the ISPAD 2022 Consensus Guidelines Chapter 14 on Other complications and associated conditions in children and adolescents with type 1 diabetes.

Remote monitoring

Mobile phone-based CGM systems have the ability to transmit glucose data to the "cloud," and allow for digital remote monitoring, whereby parents/caregivers are able to view a person's CGM tracing and receive alerts on their own devices, such as smartphones, tablets, and smart watches. Remote monitoring of CGM has been reported to improve several psychosocial outcomes in parents of children with diabetes, including quality of life, reduced family stress, and improved parental sleep.[119,120,130] Parents may have increased comfort in leaving their children with other caregivers (e.g., daycare, school, babysitters, etc.), given their awareness of the child's glucose levels and well-being from afar with remote CGM monitoring.[120] Remote monitoring

of CGM data in the school setting may enable a collaborative approach to diabetes management between the student with diabetes, parents, and school personnel.[110]

Parental fear of hypoglycemia has been associated with suboptimal glycemia in children with diabetes, especially hypoglycemia during the night-time.[131] The ability to remotely monitor CGM data has been shown to prevent prolonged nocturnal hypoglycemia in youth with diabetes.[132] The peace of mind afforded by the ability to monitor CGM data remotely and receive real-time alerts for glucose excursions enables better parental sleep,[119,120,130] and possibly comfort with in-range glucose values to improve overall glycemia.

However, conflicts can also arise because of remote monitoring of CGM data.[120] For example, youth with diabetes may have the feeling of being "policed" by their loved one, resulting in feelings of frustration. On the other hand, remote caregivers might experience unnecessary panic in certain situations such as falsely low alerts due to compression. This highlights the need for constructive communication around diabetes management with clear expectations regarding when and how caregivers should intervene based on remote monitoring of glucose data and alerts received. This is particularly important in adolescents who may desire increasing autonomy in diabetes management but can still benefit from the support of their parents and other caregivers.

Telemedicine

CGM is a helpful tool for facilitating real-time data sharing via web-based software solutions in the context of telemedicine visits so that healthcare professionals have retrospective glucose data for review. This allows healthcare professionals to easily review and interpret glucose data to make recommendations on therapy adjustments during telemedicine consultations. To that end, CGM use has become fundamental to effective remote diabetes care delivery, as cloud-based data acquisition can support meaningful interactions between families and the diabetes team. The COVID-19 pandemic in early 2020 accelerated the widespread adoption of telemedicine and remote person engagement.[133] Pediatric diabetes centers were among those who rapidly expanded telemedicine services to facilitate person care.[134,135]

Many observational studies regarding the utility of CGM were conducted during the COVID-19 pandemic.[136] However, solid evidence demonstrating the benefit of utilizing CGM data via telemedicine in improving clinical outcomes in youth with diabetes are lacking, but it will likely remain an important tool well beyond the COVID-19 pandemic. To achieve the greatest benefit from CGM, persons with T1D and caregivers may need more frequent touchpoints via telemedicine with the diabetes care team to learn how to leverage its full potential.

Despite the widespread adoption of telemedicine for people with diabetes and one of its key elements, that is, remote availability of glucose data for simultaneous review by people with diabetes and their healthcare professionals, socio-economic factors, including poverty and limited access to diabetes technology pose major obstacles to realizing its successful application. ISPAD advocates for more availability and equal access to diabetes technology for all people with diabetes.

4 | QUALITY OF LIFE AND PERSON WITH DIABETES PERSPECTIVES ON USE OF CGM

Uptake and continuous use of diabetes devices and technologies are associated with psychosocial and family factors. Psychosocial factors are broadly defined as behavioral, emotional, and social variables that characterize an individual across both dimensions of promoting health (e.g., resilience) and having negative effects on health (e.g., depression). The focus on psychosocial factors in relation to diabetes device and technology use has grown out of the broader interest in understanding how these factors impact diabetes management and health outcomes. For example, it is well established that personal strength and resilience factors, along with positive family communication, are associated with optimal management and outcomes.[137–139] Likewise, psychosocial factors such as diabetes distress, depression, and family conflict are common in youth with diabetes and often lead to suboptimal management and outcomes.[140–143] Herein, the current understanding of the association between psychosocial factors and CGM use will be highlighted.

ISPAD guidelines on the psychosocial care of youth and the American Diabetes Association guidelines for the psychosocial care of people with diabetes[144,145] highlight that attending to the psychosocial needs of all youth and their families is critical. Please refer to ISPAD 2022 Consensus Guidelines Chapter 15 on Psychological care of children and adolescents with type 1 diabetes.

Similarly, when considering whether diabetes devices and technologies should be recommended or encouraged, understanding the psychosocial aspects of the user and family will help optimize a good fit for the device. The most evidence is available for insulin pumps and CGM. CGM is linked to optimal glycemic outcomes and many users report greater treatment satisfaction.[146,147] There are also recent reports of significant alleviation of diabetes distress, worries about hypoglycemia, and improved general well-being.[148,149] Further, there are benefits of using CGM early in the course of type of diabetes[150] and during the global pandemic.[151] Person-reported outcomes have become integral and accepted parts of randomized trials on CGM, and offer a broader view of the lived experience of using devices in T1D management.[70] While there are significant benefits of CGM use, there are also reports of heightened worries[152,153] among adolescents and young adults and many discontinue CGM for a variety of reasons including cost, too many alarms, concerns about accuracy, and discomfort wearing a device on one's body.[154] Thus, setting realistic expectations for potential users and their families and providing referrals for any psychosocial need that may serve as a barrier to optimal use, are indicated. In addition, the following recommendations are made when considering CGM use (and more broadly device and technology use) in diabetes care practices:

- Portray the use of diabetes devices and technologies as an option that can be a good fit for many youth and families; provide education and encourage youth and families to review vetted websites and device informational materials.
- Encourage uptake and refrain from having youth and families "earn" the right to use devices (i.e., the requirement to achieve a

certain hemoglobin HbA1c level before considering starting a device). If payers/insurance companies require logging or other documentation prior to device approval, convey that information as a specific requirement of the payor and not an expectation of the diabetes care practice.

- Conduct a brief assessment of expectations and barriers to uptake and use. Common barriers are cost (often noted by parents of youth, and the youth themselves,[155] wearing multiple devices, sensation of wearing a device on a changing and growing body, frequent alarms and maintenance of device.
- Problem solve with the youth and their family on ways to break down barriers. This may require referral to a psychological care provider to teach problem solving skills.[144]
- If psychosocial needs are reported or identified, refer to psychological care provider.[144]
- Support youth and families in initiating CGM use, interpreting and using the CGM data to optimize diabetes management and reduce diabetes burden.

Beyond CGM, the use of other devices and technologies provides additional advice for prescribers and supporters of diabetes devices For example, in a report of 284 potential users of closed loop in the US and UK,[156] three themes were identified as critical for uptake: developing trust in the system and degree of control of it; features of the closed loop systems; and concerns about the everyday barriers to adoption. Of note, children and adolescents differed from parents in that youth primarily identified needs specific to their immediate contexts (e.g., school and peers). Parents were most concerned about the accuracy and ensuring that systems stabilize glucose levels and reduce risk for long-term complications. Other reports emphasize these same ideas of setting realistic expectations[157,158] and potential benefits on quality of life and well-being are already being realized with closed-loop systems.[147,159,160] In the United States, the FDA recognized the first Medical Device Development Tool (MDDT) as the INSPIRE scales, a person reported outcome survey evaluating expectations and well-being related to device use.[161] This can be considered when formally evaluating programs for initiating and sustaining device use.

In sum, the current evidence base points to psychosocial and quality of life benefits from using CGM and other devices such as hybrid closed loop systems. Interventions to reduce barriers to technology use are actively being investigated.[154] However, more clinically-translatable research, specifically conducted in the pediatric population is needed on the best ways to break down barriers to device and technology use and prevent discontinuation. This likely rests in setting realistic expectations, teaching effective problem-solving skills (general and technology-specific), and viewing digital health applications as a scaffolding for youth to internalize the salience and routine of specific health behaviors.

5 | CONCLUSIONS

Over the past 30 years, glucose monitoring has evolved from urine glucose testing and fingerstick capillary BG measurements to continuous glucose monitoring systems using factory-calibrated interstitial sensor technology. Along with significant improvements in CGM technology (including accuracy, device size, prolonged sensor lifetime, and user-friendliness), wider availability of CGM systems due to better coverage by national and private insurance in more parts of the world and demonstrated benefits of their application compared to SMBG in T1D, CGM has become standard of care for people with T1D in many countries.

Today, CGM technology is at the heart of diabetes management. CGM specific metrics, in particular "TIR" (defined as percentage of time with sensor readings between 70 and 180 mg/dl, 3.9 and 10 mmol/L) have been adopted as useful clinical markers[162] and outcome measurements[100] that supersede or complement HbA1c for a wide range of people with diabetes (see ISPAD 2022 Consensus Guidelines Chapter on Glycemic Targets). Manual or automated upload of CGM data to cloud-based platforms enables sharing and remote reviewing of the data. This has been and will continue to be instrumental in providing telemedical care during the COVID-19 pandemic and beyond. Particularly noteworthy, significant progress has been made in CGM-enabled algorithm-driven automated insulin delivery (AID) delivery in the form of a hybrid artificial pancreas (see ISPAD 2022 Consensus Guidelines Chapter on Insulin Delivery).

With the advent of factory-calibrated CGM sensors licensed for non-adjuvant use, it seems as if SMBG has started to take a back seat in glucose monitoring. However, it still has an important role. Even users of AID systems with calibration-free non-adjuvant CGM still have to perform capillary BG measurements in certain situations, that is, if sensor readings and personal perception do not match, to confirm hypoglycemia, to do manual calibrations if sensor readings are not accurate, and when no CGM data are available.

Of course, people who do not have access to CGM will still rely on SMBG devices. CGM devices and sensors are expensive and may not be available in many countries. Insurance coverage may also be limited. Over time, these devices will continue to become more widely available and better coverage by both national and private insurance is anticipated. ISPAD advocates for increased availability of CGM for children, adolescents, and young adults with diabetes. Where available, CGM should be initiated in all children, adolescents, and young adults with T1D as soon as possible after diagnosis.

This chapter has reviewed evidence on glucose monitoring technology in children, adolescents, and young adults. Recommendations on their use and practical advice regarding their applications has been provided. Since this is a rapidly evolving area of research and practice, further innovations and updates are to be expected.

CONFLICT OF INTEREST

Martin Tauschman reports having received speaker honoraria from Eli Lilly, Medtronic, and NovoNordisk. Martin Tauschman has served on an advisory board of Abbott. Daniel J. DeSalvo has served as an independent consultant for Dexcom and Insulet. Lori M. Laffel is a consultant/advisor to Dexcom, Insulet, Medtronic, and Roche. Dmitry N. Laptev has received honoraria for participation on advisory boards for Abbott, Novo Nordisk, Sanofi, Eli Lilly, and LifeScan and as a speaker for

Abbott, LifeScan, Medtronic, Novo Nordisk, Sanofi, and Roche. Linda A. DiMeglio has consulted for Vertex, served on Mannkind, Merck, and Abata advisory boards, and received research support to her institution from Caladrius, Lilly, Mannkind, Medtronic, Provention, and Zealand All other authors have no relevant COI to report.

REFERENCES

1. Diabetes Control and Complications Trial Research Group, Nathan DM, Genuth S, et al. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The diabetes control and complications trial research group. *N Engl J Med*. 1993;329(14):977-986. doi:10.1056/nejm199309303291401
2. Cardona-Hernandez R, Schwandt A, Alkandari H, et al. Glycemic outcome associated with insulin pump and glucose sensor use in children and adolescents with T1D. Data from the international pediatric registry SWEET. *Diabetes Care*. 2021;44(5):1176-1184. doi:10.2337/dc20-1674
3. Maiorino MI, Signoriello S, Maio A, et al. Effects of continuous glucose monitoring on metrics of glycemic control in diabetes: a systematic review with meta-analysis of randomized controlled trials. *Diabetes Care*. 2020;43(5):1146-1156. doi:10.2337/dc19-1459
4. King F, Ahn D, Hsiao V, Porco T, Klonoff DC. A review of blood glucose monitor accuracy. *Diabetes Technol Ther*. 2018;20(12):843-856. doi:10.1089/dia.2018.0232
5. International Standards Organization. ISO 15197:2013. In vitro diagnostic test systems – requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. Accessed February 5, 2022. https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/05/49/54976.html
6. U.S. Food and Drug Administration. Blood Glucose Monitoring Test Systems for Over-the-Counter Use: Guidance for Industry and Food and Drug Administration Staff. Accessed February 5, 2022. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoringblood-glucose-test-systems-over-counter-use
7. U.S. Food and Drug Administration. Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use: Guidance for Industry and Food and Drug Administration Staff. Accessed February 5, 2022. https://www.fda.gov/regulatory-information/search-fdaguidance-documents/blood-glucose-monitoringtest-systems-prescription-point-care-use
8. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care*. 2000;23(8):1143-1148. doi:10.2337/diacare.23.8.1143
9. Hirose T, Mita T, Fujitani Y, Kawamori R, Watada H. Glucose monitoring after fruit peeling: pseudohyperglycemia when neglecting hand washing before fingertip blood sampling: wash your hands with tap water before you check blood glucose level. *Diabetes Care*. 2011;34(3):596-597. doi:10.2337/dc10-1705
10. Ginsberg BH. Factors affecting blood glucose monitoring: sources of errors in measurement. *J Diabetes Sci Technol*. 2009;3(4):903-913. doi:10.1177/193229680900300438
11. Ziegler R, Cavan DA, Cranston I, et al. Use of an insulin bolus advisor improves glycemic control in multiple daily insulin injection (MDI) therapy patients with suboptimal glycemic control: first results from the ABACUS trial. *Diabetes Care*. 2013;36(11):3613-3619. doi:10.2337/dc13-0251
12. Vallejo Mora MDR, Carreira M, Anarte MT, Linares F, Olveira G, González RS. Bolus calculator reduces hypoglycemia in the short term and fear of hypoglycemia in the long term in subjects with (CBMDI study). *Diabetes Technol Ther*. 2017;19(7):402-409. doi:10.1089/dia.2017.0019
13. Vallejo-Mora MD, Carreira-Soler M, Linares-Parrado F, et al. The calculating boluses on multiple daily injections (CBMDI) study: a randomized controlled trial on the effect on metabolic control of adding a bolus calculator to multiple daily injections in people with type 1 diabetes. *J Diabetes*. 2017;9(1):24-33. doi:10.1111/1753-0407.12382
14. Haller MJ, Stalvey MS, Silverstein JH. Predictors of control of diabetes: monitoring may be the key. *J Pediatr*. 2004;144(5):660-661. doi:10.1016/j.jpeds.2003.12.042
15. Ziegler R, Heidtmann B, Hilgard D, et al. Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes. *Pediatr Diabetes*. 2011;12(1):11-17. doi:10.1111/j.1399-5448.2010.00650.x
16. Miller KM, Beck RW, Bergenstal RM, et al. Evidence of a strong association between frequency of self-monitoring of blood glucose and hemoglobin A1c levels in T1D exchange clinic registry participants. *Diabetes Care*. 2013;36(7):2009-2014. doi:10.2337/dc12-1770
17. Miller KM, Hermann J, Foster N, et al. Longitudinal changes in continuous glucose monitoring use among individuals with type 1 diabetes: international comparison in the German and Austrian DPV and U.S. T1D exchange registries. *Diabetes Care*. 2020;43(1):e1-e2. doi:10.2337/dc19-1214
18. Desalvo D, Lanzinger S, Noor N, et al. 616-P: CGM use and A1C: a transatlantic comparison of the DPV initiative and T1D exchange quality improvement collaborative (T1DX-QI) (poster). *Diabetes*. 2021;70:616. doi:10.2337/db21-616-P
19. Johnson SR, Holmes-Walker DJ, Chee M, et al. Universal subsidized continuous glucose monitoring funding for Young people with type 1 diabetes: uptake and outcomes over 2 years, a population-based study. *Diabetes Care*. 2022;45(2):391-397. doi:10.2337/dc21-1666
20. Addala A, Auzanneau M, Miller K, et al. A decade of disparities in diabetes technology use and HbA(1c) in pediatric type 1 diabetes: a transatlantic comparison. *Diabetes Care*. 2021;44(1):133-140. doi:10.2337/dc20-0257
21. Prahalad P, Ebekozien O, Alonso GT, et al. Multi-clinic quality improvement initiative increases continuous glucose monitoring use among adolescents and Young adults with type 1 diabetes. *Clin Diabetes*. 2021;39(3):264-271. doi:10.2337/cd21-0026
22. Garg SK, Liljenquist D, Bode B, et al. Evaluation of accuracy and safety of the next-generation up to 180-day long-term implantable Eversense continuous glucose monitoring system: the PROMISE study. *Diabetes Technol Ther*. 2021;24:84-92. doi:10.1089/dia.2021.0182
23. Bailey T, Bode BW, Christiansen MP, Klaff LJ, Alva S. The performance and usability of a factory-calibrated flash glucose monitoring system. *Diabetes Technol Ther*. 2015;17(11):787-794. doi:10.1089/dia.2014.0378
24. Alva S, Bailey T, Brazg R, et al. Accuracy of a 14-day factory-calibrated continuous glucose monitoring system with advanced algorithm in pediatric and adult population with diabetes. *J Diabetes Sci Technol*. 2022;16(1):70-77. doi:10.1177/1932296820958754
25. Basu A, Dube S, Veettil S, et al. Time lag of glucose from intravascular to interstitial compartment in type 1 diabetes. *J Diabetes Sci Technol*. 2015;9(1):63-68. doi:10.1177/1932296814554797
26. Keenan DB, Mastrototaro JJ, Voskanyan G, Steil GM. Delays in minimally invasive continuous glucose monitoring devices: a review of current technology. *J Diabetes Sci Technol*. 2009;3(5):1207-1214. doi:10.1177/193229680900300528
27. Sinha M, McKeon KM, Parker S, et al. A comparison of time delay in three continuous glucose monitors for adolescents and adults. *J Diabetes Sci Technol*. 2017;11(6):1132-1137. doi:10.1177/1932296817704443
28. Helton KL, Ratner BD, Wisniewski NA. Biomechanics of the sensor-tissue interface-effects of motion, pressure, and design on sensor performance and foreign body response-part II: examples and

application. *J Diabetes Sci Technol*. 2011;5(3):647-656. doi:10.1177/193229681100500318
29. Heinemann L, Schoemaker M, Schmelzeisen-Redecker G, et al. Benefits and limitations of MARD as a performance parameter for continuous glucose monitoring in the interstitial space. *J Diabetes Sci Technol*. 2020;14(1):135-150. doi:10.1177/1932296819855670
30. Christiansen MP, Klaff LJ, Bailey TS, Brazg R, Carlson G, Tweden KS. A prospective multicenter evaluation of the accuracy and safety of an implanted continuous glucose sensor: the PRECISION study. *Diabetes Technol Ther*. 2019;21(5):231-237. doi:10.1089/dia.2019.0020
31. Shah VN, Laffel LM, Wadwa RP, Garg SK. Performance of a factory-calibrated real-time continuous glucose monitoring system utilizing an automated sensor applicator. *Diabetes Technol Ther*. 2018;20(6):428-433. doi:10.1089/dia.2018.0143
32. Jafri RZ, Balliro CA, El-Khatib F, et al. A three-way accuracy comparison of the Dexcom G5, Abbott Freestyle libre pro, and Senseonics Eversense continuous glucose monitoring devices in a home-use study of subjects with type 1 diabetes. *Diabetes Technol Ther*. 2020;22(11):846-852. doi:10.1089/dia.2019.0449
33. U.S. Food and Drug Administration. CFR - Code of Federal Regulations Title 21. Accessed September 30, 2022. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=862.1355
34. Tellez SE, Hornung LN, Courter JD, et al. Inaccurate glucose sensor values after hydroxyurea administration. *Diabetes Technol Ther*. 2021;23(6):443-451. doi:10.1089/dia.2020.0490
35. Basu A, Veettil S, Dyer R, Peyser T, Basu R. Direct evidence of acetaminophen interference with subcutaneous glucose sensing in humans: a pilot study. *Diabetes Technol Ther*. 2016;18(Suppl 2):S243-S247. doi:10.1089/dia.2015.0410
36. Maahs DM, DeSalvo D, Pyle L, et al. Effect of acetaminophen on CGM glucose in an outpatient setting. *Diabetes Care*. 2015;38(10):e158-e159. doi:10.2337/dc15-1096
37. U.S. Food and Drug Administration. Approved products: Freestyle Libre. www.accessdata.fda.gov/cdrh_docs/pdf16/P160030C.pdf
38. Basu A, Slama MQ, Nicholson WT, et al. Continuous glucose monitor interference with commonly prescribed medications: a pilot study. *J Diabetes Sci Technol*. 2017;11(5):936-941. doi:10.1177/1932296817697329
39. Mortellaro M, DeHennis A. Performance characterization of an abiotic and fluorescent-based continuous glucose monitoring system in patients with type 1 diabetes. *Biosens Bioelectron*. 2014;61:227-231. doi:10.1016/j.bios.2014.05.022
40. Hoss U, Budiman ES. Factory-calibrated continuous glucose sensors: the science behind the technology. *Diabetes Technol Ther*. 2017;19(S2):S44-S50. doi:10.1089/dia.2017.0025
41. Kovatchev BP, Patek SD, Ortiz EA, Breton MD. Assessing sensor accuracy for non-adjunct use of continuous glucose monitoring. *Diabetes Technol Ther*. 2015;17(3):177-186. doi:10.1089/dia.2014.0272
42. Aleppo G, Ruedy KJ, Riddlesworth TD, et al. REPLACE-BG: a randomized trial comparing continuous glucose monitoring with and without routine blood glucose monitoring in adults with well-controlled type 1 diabetes. *Diabetes Care*. 2017;40(4):538-545. doi:10.2337/dc16-2482
43. Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. *BMJ*. 2011;343:d3805.
44. Langendam M, Luijf YM, Hooft L, Devries JH, Mudde AH, Scholten RJ. Continuous glucose monitoring systems for type 1 diabetes mellitus. *Cochrane Database Syst Rev*. 2012;2012:Cd008101. doi:10.1002/14651858.CD008101.pub2
45. Szypowska A, Ramotowska A, Dzygalo K, Golicki D. Beneficial effect of real-time continuous glucose monitoring system on glycemic control in type 1 diabetic patients: systematic review and meta-analysis of randomized trials. *Eur J Endocrinol*. 2012;166(4):567-574. doi:10.1530/EJE-11-0642
46. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study G, Tamborlane WV, Beck RW, et al. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *N Engl J Med*. 2008;359(14):1464-1476. doi:10.1056/NEJMoa0805017
47. Beck RW, Buckingham B, Miller K, et al. Factors predictive of use and of benefit from continuous glucose monitoring in type 1 diabetes. *Diabetes Care*. 2009;32(11):1947-1953. doi:10.2337/dc09-0889
48. Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes. *N Engl J Med*. 2010;363(4):311-320. doi:10.1056/NEJMoa1002853
49. Battelino T, Phillip M, Bratina N, Nimri R, Oskarsson P, Bolinder J. Effect of continuous glucose monitoring on hypoglycemia in type 1 diabetes. *Diabetes Care*. 2011;34(4):795-800. doi:10.2337/dc10-1989
50. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: the DIAMOND randomized clinical trial. *JAMA*. 2017;317(4):371-378. doi:10.1001/jama.2016.19975
51. El-Laboudi AH, Godsland IF, Johnston DG, Oliver NS. Measures of glycemic variability in type 1 diabetes and the effect of real-time continuous glucose monitoring. *Diabetes Technol Ther*. 2016;18(12):806-812. doi:10.1089/dia.2016.0146
52. Dicembrini I, Cosentino C, Monami M, Mannucci E, Pala L. Effects of real-time continuous glucose monitoring in type 1 diabetes: a meta-analysis of randomized controlled trials. *Acta Diabetol*. 2021;58(4):401-410. doi:10.1007/s00592-020-01589-3
53. Foster NC, Miller KM, Tamborlane WV, Bergenstal RM, Beck RW, Network TDEC. Continuous glucose monitoring in patients with type 1 diabetes using insulin injections. *Diabetes Care*. 2016;39(6):e81-e82. doi:10.2337/dc16-0207
54. Lind M, Polonsky W, Hirsch IB, et al. Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: the GOLD randomized clinical trial. *JAMA*. 2017;317(4):379-387. doi:10.1001/jama.2016.19976
55. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. *Lancet*. 2016;388(10057):2254-2263. doi:10.1016/S0140-6736(16)31535-5
56. Šoupal J, Petruželková L, Grunberger G, et al. Glycemic outcomes in adults with T1D are impacted more by continuous glucose monitoring than by insulin delivery method: 3 years of follow-up from the COMISAIR study. *Diabetes Care*. 2020;43(1):37-43. doi:10.2337/dc19-0888
57. Miller KM, Beck RW, Foster NC, Maahs DM. HbA1c levels in type 1 diabetes from early childhood to older adults: a deeper dive into the influence of technology and socioeconomic status on HbA1c in the T1D exchange clinic registry findings. *Diabetes Technol Ther*. 2020;22(9):645-650. doi:10.1089/dia.2019.0393
58. Wong JC, Foster NC, Maahs DM, et al. Real-time continuous glucose monitoring among participants in the T1D exchange clinic registry. *Diabetes Care*. 2014;37(10):2702-2709. doi:10.2337/dc14-0303
59. Tauschmann M, Hermann JM, Freiberg C, et al. Reduction in diabetic ketoacidosis and severe hypoglycemia in pediatric type 1 diabetes during the first year of continuous glucose monitoring: a multicenter analysis of 3,553 subjects from the DPV registry. *Diabetes Care*. 2020;43(3):e40-e42. doi:10.2337/dc19-1358
60. Ludwig-Seibold CU, Holder M, Rami B, et al. Continuous glucose monitoring in children, adolescents, and adults with type 1 diabetes mellitus: analysis from the prospective DPV diabetes documentation and quality management system from Germany and Austria.

Pediatr Diabetes. 2012;13(1):12-14. doi:10.1111/j.1399-5448.2011.00835.x
61. DeSalvo DJ, Miller KM, Hermann JM, et al. Continuous glucose monitoring and glycemic control among youth with type 1 diabetes: international comparison from the T1D exchange and DPV initiative. *Pediatr Diabetes*. 2018;19(7):1271-1275. doi:10.1111/pedi.12711
62. Foster NC, Beck RW, Miller KM, et al. State of type 1 diabetes management and outcomes from the T1D exchange in 2016–2018. *Diabetes Technol Ther*. 2019;21(2):66-72. doi:10.1089/dia.2018.0384
63. van den Boom L, Karges B, Auzanneau M, et al. Temporal trends and contemporary use of insulin pump therapy and glucose monitoring among children, adolescents, and adults with type 1 diabetes between 1995 and 2017. *Diabetes Care*. 2019;42(11):2050-2056. doi:10.2337/dc19-0345
64. Sundberg F, Nåtman J, Franzen S, Åkesson K, Särnblad S. A decade of improved glycemic control in young children with type 1 diabetes: a population-based cohort study. *Pediatr Diabetes*. 2021;22(5):742-748. doi:10.1111/pedi.13211
65. Sumnik Z, Szypowska A, Iotova V, et al. Persistent heterogeneity in diabetes technology reimbursement for children with type 1 diabetes: the SWEET perspective. *Pediatr Diabetes*. 2019;20(4):434-443. doi:10.1111/pedi.12833
66. Charleer S, De Block C, Van Huffel L, et al. Quality of life and glucose control after 1 year of Nationwide reimbursement of intermittently scanned continuous glucose monitoring in adults living with type 1 diabetes (FUTURE): a prospective observational real-world cohort study. *Diabetes Care*. 2020;43(2):389-397. doi:10.2337/dc19-1610
67. Deshmukh H, Wilmot EG, Gregory R, et al. Effect of flash glucose monitoring on glycemic control, hypoglycemia, diabetes-related distress, and resource utilization in the Association of British Clinical Diabetologists (ABCD) Nationwide audit. *Diabetes Care*. 2020;43(9):2153-2160. doi:10.2337/dc20-0738
68. Patton SR, Noser AE, Youngkin EM, Majidi S, Clements MA. Early initiation of diabetes devices relates to improved glycemic control in children with recent-onset type 1 diabetes mellitus. *Diabetes Technol Ther*. 2019;21(7):379-384. doi:10.1089/dia.2019.0026
69. Mulinacci G, Alonso GT, Snell-Bergeon JK, Shah VN. Glycemic outcomes with early initiation of continuous glucose monitoring system in recently diagnosed patients with type 1 diabetes. *Diabetes Technol Ther*. 2019;21(1):6-10. doi:10.1089/dia.2018.0257
70. Laffel LM, Kanapka LG, Beck RW, et al. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. *JAMA*. 2020;323(23):2388-2396. doi:10.1001/jama.2020.6940
71. Thabit H, Prabhu JN, Mubita W, et al. Use of factory-calibrated real-time continuous glucose monitoring improves time in target and HbA. *Diabetes Care*. 2020;43(10):2537-2543. doi:10.2337/dc20-0736
72. Addala A, Maahs DM, Scheinker D, Chertow S, Leverenz B, Prahalad P. Uninterrupted continuous glucose monitoring access is associated with a decrease in HbA1c in youth with type 1 diabetes and public insurance. *Pediatr Diabetes*. 2020;21(7):1301-1309. doi:10.1111/pedi.13082
73. Jeha GS, Karaviti LP, Anderson B, et al. Continuous glucose monitoring and the reality of metabolic control in preschool children with type 1 diabetes. *Diabetes Care*. 2004;27(12):2881-2886.
74. Gandrud LM, Xing D, Kollman C, et al. The Medtronic Minimed Gold continuous glucose monitoring system: an effective means to discover hypo- and hyperglycemia in children under 7 years of age. *Diabetes Technol Ther*. 2007;9(4):307-316. doi:10.1089/dia.2007.0026
75. Dovc K, Cargnelutti K, Sturm A, Selb J, Bratina N, Battelino T. Continuous glucose monitoring use and glucose variability in pre-school children with type 1 diabetes. *Diabetes Res Clin Pract*. 2019;147:76-80. doi:10.1016/j.diabres.2018.10.005
76. A Randomized Clinical Trial Assessing Continuous Glucose Monitoring (CGM). Use with standardized education with or without a family behavioral intervention compared with fingerstick blood glucose monitoring in very Young children with type 1 diabetes. *Diabetes Care*. 2021;44(2):464-472. doi:10.2337/dc20-1060
77. Boucher SE, Gray AR, Wiltshire EJ, et al. Effect of 6 months of flash glucose monitoring in youth with type 1 diabetes and high-risk glycemic control: a randomized controlled trial. *Diabetes Care*. 2020;43(10):2388-2395. doi:10.2337/dc20-0613
78. Oskarsson P, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R, Bolinder J. Impact of flash glucose monitoring on hypoglycaemia in adults with type 1 diabetes managed with multiple daily injection therapy: a pre-specified subgroup analysis of the IMPACT randomised controlled trial. *Diabetologia*. 2018;61(3):539-550. doi:10.1007/s00125-017-4527-5
79. Boucher SE, Aum SH, Crocket HR, et al. Exploring parental perspectives after commencement of flash glucose monitoring for type 1 diabetes in adolescents and young adults not meeting glycaemic targets: a qualitative study. *Diabet Med*. 2020;37(4):657-664. doi:10.1111/dme.14188
80. Campbell FM, Murphy NP, Stewart C, Biester T, Kordonouri O. Outcomes of using flash glucose monitoring technology by children and young people with type 1 diabetes in a single arm study. *Pediatr Diabetes*. 2018;19(7):1294-1301. doi:10.1111/pedi.12735
81. Landau Z, Abiri S, Gruber N, et al. Use of flash glucose-sensing technology (FreeStyle libre) in youth with type 1 diabetes: AWeSoMe study group real-life observational experience. *Acta Diabetol*. 2018;55(12):1303-1310. doi:10.1007/s00592-018-1218-8
82. Ish-Shalom M, Wainstein J, Raz I, Mosenzon O. Improvement in glucose control in difficult-to-control patients with diabetes using a novel flash glucose monitoring device. *J Diabetes Sci Technol*. 2016;10(6):1412-1413. doi:10.1177/1932296816653412
83. Dover AR, Stimson RH, Zammitt NN, Gibb FW. Flash glucose monitoring improves outcomes in a type 1 diabetes clinic. *J Diabetes Sci Technol*. 2017;11(2):442-443. doi:10.1177/1932296816661560
84. McKnight JA, Gibb FW. Flash glucose monitoring is associated with improved glycaemic control but use is largely limited to more affluent people in a UK diabetes Centre. *Diabet Med*. 2017;34(5):732. doi:10.1111/dme.13315
85. Bahíllo-Curieses MP, Díaz-Soto G, Vidueira-Martínez AM, Torres-Ballester I, Gómez-Hoyos E, de Luis-Román D. Assessment of metabolic control and use of flash glucose monitoring systems in a cohort of pediatric, adolescents, and adults patients with type 1 diabetes. *Endocrine*. 2021;73(1):47-51. doi:10.1007/s12020-021-02691-4
86. Biester T, Grimsmann JM, Heidtmann B, et al. Intermittently scanned glucose values for continuous monitoring: cross-sectional analysis of glycemic control and hypoglycemia in 1809 children and adolescents with type 1 diabetes. *Diabetes Technol Ther*. 2021;23(3):160-167. doi:10.1089/dia.2020.0373
87. Suzuki J, Urakami T, Yoshida K, et al. Association between scanning frequency of flash glucose monitoring and continuous glucose monitoring-derived glycemic makers in children and adolescents with type 1 diabetes. *Pediatr Int*. 2021;63(2):154-159. doi:10.1111/ped.14412
88. Urakami T, Yoshida K, Kuwabara R, et al. Frequent scanning using flash glucose monitoring contributes to better glycemic control in children and adolescents with type 1 diabetes. *J Diabetes Investig*. 2022;13(1):185-190. doi:10.1111/jdi.13618
89. Dunn TC, Xu Y, Hayter G, Ajjan RA. Real-world flash glucose monitoring patterns and associations between self-monitoring frequency and glycaemic measures: a European analysis of over 60 million glucose tests. *Diabetes Res Clin Pract*. 2018;137:37-46. doi:10.1016/j.diabres.2017.12.015
90. Gomez-Peralta F, Dunn T, Landuyt K, Xu Y, Merino-Torres JF. Flash glucose monitoring reduces glycemic variability and hypoglycemia:

real-world data from Spain. *BMJ Open Diabetes Res Care*. 2020;8(1):1052. doi:10.1136/bmjdrc-2019-001052
91. Jeyam A, Gibb FW, McKnight JA, et al. Flash monitor initiation is associated with improvements in HbA. *Diabetologia*. 2022;65(1):159-172. doi:10.1007/s00125-021-05578-1
92. Massa GG, Gys I, Bevilacqua E, Wijnands A, Zeevaert R. Comparison of flash glucose monitoring with real time continuous glucose monitoring in children and adolescents with type 1 diabetes treated with continuous subcutaneous insulin infusion. *Diabetes Res Clin Pract*. 2019;152:111-118. doi:10.1016/j.diabres.2019.05.015
93. Préau Y, Galie S, Schaepelynck P, Armand M, Raccah D. Benefits of a switch from intermittently scanned continuous glucose monitoring (isCGM) to real-time (rt) CGM in diabetes type 1 suboptimal controlled patients in real-life: a one-year prospective study (§). *Sensors*. 2021;21(18):6131. doi:10.3390/s21186131
94. Hásková A, Radovnická L, Petruželková L, et al. Real-time CGM is superior to flash glucose monitoring for glucose control in type 1 diabetes: the CORRIDA randomized controlled trial. *Diabetes Care*. 2020;43(11):2744-2750. doi:10.2337/dc20-0112
95. Nirantharakumar K, Mohammed N, Toulis KA, Thomas GN, Narendran P. Clinically meaningful and lasting HbA (1c) improvement rarely occurs after 5 years of type 1 diabetes: an argument for early, targeted and aggressive intervention following diagnosis. *Diabetologia*. 2018;61(5):1064-1070. doi:10.1007/s00125-018-4574-6
96. Champakanath A, Akturk HK, Alonso GT, Snell-Bergeon JK, Shah VN. Continuous glucose monitoring initiation within first year of type 1 diabetes diagnosis is associated with improved glycemic outcomes: 7-year follow-up study. *Diabetes Care*. 2022;45(3):750-753. doi:10.2337/dc21-2004
97. Bonfanti R, Bazzigaluppi E, Calori G, et al. Parameters associated with residual insulin secretion during the first year of disease in children and adolescents with type 1 diabetes mellitus. *Diabet Med*. 1998;15(10):844-850. doi:10.1002/(sici)1096-9136(199810)15:10<844::Aid-dia679>3.0.Co;2-a
98. The Diabetes Control and Complications Trial Research Group. Effect of intensive therapy on residual beta-cell function in patients with type 1 diabetes in the diabetes control and complications trial. A randomized, controlled trial. The DCCT research group. *Ann Intern Med*. 1998;128(7):517-523.
99. Nathan DM. The diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: overview. *Diabetes Care*. 2014;37(1):9-16. doi:10.2337/dc13-2112
100. Beck RW, Bergenstal RM, Riddlesworth TD, et al. Validation of time in range as an outcome measure for diabetes clinical trials. *Diabetes Care*. 2019;42(3):400-405. doi:10.2337/dc18-1444
101. Steck AK, Dong F, Taki I, et al. Continuous glucose monitoring predicts progression to diabetes in autoantibody positive children. *J Clin Endocrinol Metab*. 2019;104(8):3337-3344. doi:10.1210/jc.2018-02196
102. Sims EK, Besser REJ, Dayan C, et al. Screening for type 1 diabetes in the general population: a status report and perspective. *Diabetes*. 2022;71(4):610-623. doi:10.2337/dbi20-0054
103. Desrochers HR, Schultz AT, Laffel LM. Use of diabetes Technology in Children: role of structured education for Young people with diabetes and families. *Endocrinol Metab Clin N Am*. 2020;49(1):19-35. doi:10.1016/j.ecl.2019.11.001
104. Bode BW, Battelino T. Continuous glucose monitoring in 2014. *Diabetes Technol Ther*. 2015;17(Suppl 1):S12-S20. doi:10.1089/dia.2015.1502
105. Lawton J, Blackburn M, Allen J, et al. Patients' and caregivers' experiences of using continuous glucose monitoring to support diabetes self-management: qualitative study. *BMC Endocr Disord*. 2018;18(1):12. doi:10.1186/s12902-018-0239-1
106. Messer L, Ruedy K, Xing D, et al. Educating families on real time continuous glucose monitoring: the DirecNet navigator pilot study experience. *Diabetes Educ*. 2009;35(1):124-135. doi:10.1177/0145721708325157
107. Ritholz MD, Atakov-Castillo A, Beste M, et al. Psychosocial factors associated with use of continuous glucose monitoring. *Diabet Med*. 2010;27(9):1060-1065. doi:10.1111/j.1464-5491.2010.03061.x
108. Lawton J, Rankin D, Cooke D, et al. Patients' experiences of adjusting insulin doses when implementing flexible intensive insulin therapy: a longitudinal, qualitative investigation. *Diabetes Res Clin Pract*. 2012;98(2):236-242. doi:10.1016/j.diabres.2012.09.024
109. Bratina N, Battelino T. Insulin pumps and continuous glucose monitoring (CGM) in preschool and school-age children: how schools can integrate technology. *Pediatr Endocrinol Rev*. 2010;7(Suppl 3):417-421.
110. Erie C, Van Name MA, Weyman K, et al. Schooling diabetes: use of continuous glucose monitoring and remote monitors in the home and school settings. *Pediatr Diabetes*. 2018;19(1):92-97. doi:10.1111/pedi.12518
111. Hirsch IB, Miller E. Integrating continuous glucose monitoring into clinical practices and patients' lives. *Diabetes Technol Ther*. 2021;23(S3):S72-s80. doi:10.1089/dia.2021.0233
112. Elbarbary N, Moser O, Al Yaarubi S, et al. Use of continuous glucose monitoring trend arrows in the younger population with type 1 diabetes. *Diab Vasc Dis Res*. 2021;18(6):14791641211062155. doi:10.1177/14791641211062155
113. Jabbour G, Henderson M, Mathieu ME. Barriers to active lifestyles in children with type 1 diabetes. *Can J Diabetes*. 2016;40(2):170-172. doi:10.1016/j.jcjd.2015.12.001
114. Riddell M, Perkins BA. Exercise and glucose metabolism in persons with diabetes mellitus: perspectives on the role for continuous glucose monitoring. *J Diabetes Sci Technol*. 2009;3(4):914-923. doi:10.1177/193229680900300439
115. Burckhardt MA, Chetty T, Smith GJ, et al. Use of continuous glucose monitoring trends to facilitate exercise in children with type 1 diabetes. *Diabetes Technol Ther*. 2019;21(1):51-55. doi:10.1089/dia.2018.0292
116. Riddell MC, Milliken J. Preventing exercise-induced hypoglycemia in type 1 diabetes using real-time continuous glucose monitoring and a new carbohydrate intake algorithm: an observational field study. *Diabetes Technol Ther*. 2011;13(8):819-825. doi:10.1089/dia.2011.0052
117. Moser O, Riddell MC, Eckstein ML, et al. Glucose management for exercise using continuous glucose monitoring (CGM) and intermittently scanned CGM (isCGM) systems in type 1 diabetes: position statement of the European Association for the study of diabetes (EASD) and of the International Society for Pediatric and Adolescent Diabetes (ISPAD) endorsed by JDRF and supported by the American Diabetes Association (ADA). *Pediatr Diabetes*. 2020;21(8):1375-1393. doi:10.1111/pedi.13105
118. Adolfsson P, Riddell MC, Taplin CE, et al. ISPAD clinical practice consensus guidelines 2018: exercise in children and adolescents with diabetes. *Pediatr Diabetes*. 2018;19:205-226. doi:10.1111/pedi.12755
119. Burckhardt MA, Roberts A, Smith GJ, Abraham MB, Davis EA, Jones TW. The use of continuous glucose monitoring with remote monitoring improves psychosocial measures in parents of children with type 1 diabetes: a randomized crossover trial. *Diabetes Care*. 2018;41(12):2641-2643. doi:10.2337/dc18-0938
120. Hilliard ME, Levy W, Anderson BJ, et al. Benefits and barriers of continuous glucose monitoring in Young children with type 1 diabetes. *Diabetes Technol Ther*. 2019;21(9):493-498. doi:10.1089/dia.2019.0142
121. Asarani NAM, Reynolds AN, Boucher SE, de Bock M, Wheeler BJ. Cutaneous complications with continuous or flash glucose

monitoring use: systematic review of trials and observational studies. *J Diabetes Sci Technol*. 2020;14(2):328-337. doi:10.1177/1932296819870849
122. Herman A, de Montjoye L, Tromme I, Goossens A, Baeck M. Allergic contact dermatitis caused by medical devices for diabetes patients: a review. *Contact Dermatitis*. 2018;79(6):331-335. doi:10.1111/cod.13120
123. Herman A, Darrigade AS, de Montjoye L, Baeck M. Contact dermatitis caused by glucose sensors in diabetic children. *Contact Dermatitis*. 2020;82(2):105-111. doi:10.1111/cod.13429
124. Burgmann J, Biester T, Grothaus J, Kordonouri O, Ott H. Pediatric diabetes and skin disease (PeDiSkin): a cross-sectional study in 369 children, adolescents and young adults with type 1 diabetes. *Pediatr Diabetes*. 2020;21(8):1556-1565. doi:10.1111/pedi.13130
125. Herman A, de Montjoye L, Baeck M. Adverse cutaneous reaction to diabetic glucose sensors and insulin pumps: irritant contact dermatitis or allergic contact dermatitis? *Contact Dermatitis*. 2020;83(1):25-30. doi:10.1111/cod.13529
126. Pyl J, Dendooven E, Van Eekelen I, et al. Prevalence and prevention of contact dermatitis caused by FreeStyle libre: a monocentric experience. *Diabetes Care*. 2020;43(4):918-920. doi:10.2337/dc19-1354
127. Hyry HSI, Liippo JP, Virtanen HM. Allergic contact dermatitis caused by glucose sensors in type 1 diabetes patients. *Contact Dermatitis*. 2019;81(3):161-166. doi:10.1111/cod.13337
128. Herman A, Uter W, Rustemeyer T, et al. Position statement: the need for EU legislation to require disclosure and labelling of the composition of medical devices. *J Eur Acad Dermatol Venereol*. 2021;35(7):1444-1448. doi:10.1111/jdv.17238
129. Messer LH, Berget C, Beatson C, Polsky S, Forlenza GP. Preserving skin integrity with chronic device use in diabetes. *Diabetes Technol Ther*. 2018;20(S2):S254-S264. doi:10.1089/dia.2018.0080
130. Burckhardt MA, Fried L, Bebbington K, et al. Use of remote monitoring with continuous glucose monitoring in young children with type 1 diabetes: the parents' perspective. *Diabet Med*. 2019;36(11):1453-1459. doi:10.1111/dme.14061
131. Van Name MA, Hilliard ME, Boyle CT, et al. Nighttime is the worst time: parental fear of hypoglycemia in young children with type 1 diabetes. *Pediatr Diabetes*. 2018;19(1):114-120. doi:10.1111/pedi.12525
132. DeSalvo DJ, Keith-Hynes P, Peyser T, et al. Remote glucose monitoring in cAMP setting reduces the risk of prolonged nocturnal hypoglycemia. *Diabetes Technol Ther*. 2014;16(1):1-7. doi:10.1089/dia.2013.0139
133. Keesara S, Jonas A, Schulman K. Covid-19 and health Care's digital revolution. *N Engl J Med*. 2020;382(23):e82. doi:10.1056/NEJMp2005835
134. Lee JM, Carlson E, Albanese-O'Neill A, et al. Adoption of telemedicine for type 1 diabetes care during the COVID-19 pandemic. *Diabetes Technol Ther*. 2021;23(9):642-651. doi:10.1089/dia.2021.0080
135. Sarteau AC, Souris KJ, Wang J, et al. Changes to care delivery at nine international pediatric diabetes clinics in response to the COVID-19 global pandemic. *Pediatr Diabetes*. 2021;22(3):463-468. doi:10.1111/pedi.13180
136. Danne T, Limbert C, Puig Domingo M, et al. Telemonitoring, telemedicine and time in range during the pandemic: paradigm change for diabetes risk Management in the Post-COVID Future. *Diabetes Ther*. 2021;12(9):2289-2310. doi:10.1007/s13300-021-01114-x
137. Katz ML, Volkening LK, Butler DA, Anderson BJ, Laffel LM. Family-based psychoeducation and care ambassador intervention to improve glycemic control in youth with type 1 diabetes: a randomized trial. *Pediatr Diabetes*. 2014;15(2):142-150. doi:10.1111/pedi.12065
138. Hilliard ME, Iturralde E, Weissberg-Benchell J, Hood KK. The diabetes strengths and resilience measure for adolescents with type 1 diabetes (DSTAR-teen): validation of a new, brief self-report measure. *J Pediatr Psychol*. 2017;42(9):995-1005. doi:10.1093/jpepsy/jsx086
139. Hilliard ME, Hagger V, Hendrieckx C, et al. Strengths, risk factors, and resilient outcomes in adolescents with type 1 diabetes: results from diabetes MILES youth-Australia. *Diabetes Care*. 2017;40(7):849-855. doi:10.2337/dc16-2688
140. Jaser SS, Patel N, Xu M, Tamborlane WV, Grey M. Stress and coping predicts adjustment and glycemic control in adolescents with type 1 diabetes. *Ann Behav Med*. 2017;51(1):30-38. doi:10.1007/s12160-016-9825-5
141. Hilliard ME, Lawrence JM, Modi AC, et al. Identification of minimal clinically important difference scores of the PedsQL in children, adolescents, and young adults with type 1 and type 2 diabetes. *Diabetes Care*. 2013;36(7):1891-1897. doi:10.2337/dc12-1708
142. Hagger V, Hendrieckx C, Sturt J, Skinner TC, Speight J. Diabetes distress among adolescents with type 1 diabetes: a systematic review. *Curr Diab Rep*. 2016;16(1):9. doi:10.1007/s11892-015-0694-2
143. Hickling A, Dingle GA, Barrett HL, Cobham VE. Systematic review: diabetes family conflict in Young people with type 1 diabetes. *J Pediatr Psychol*. 2021;46(9):1091-1109. doi:10.1093/jpepsy/jsab052
144. Young-Hyman D, de Groot M, Hill-Briggs F, Gonzalez JS, Hood K, Peyrot M. Psychosocial care for People with diabetes: a position statement of the American Diabetes Association. *Diabetes Care*. 2016;39(12):2126-2140. doi:10.2337/dc16-2053
145. Chiang JL, Maahs DM, Garvey KC, et al. Type 1 diabetes in children and adolescents: a position statement by the American Diabetes Association. *Diabetes Care*. 2018;41(9):2026-2044. doi:10.2337/dci18-0023
146. Ng SM, Moore HS, Clemente MF, Pintus D, Soni A. Continuous glucose monitoring in children with type 1 diabetes improves well-being, alleviates worry and fear of hypoglycemia. *Diabetes Technol Ther*. 2019;21(3):133-137. doi:10.1089/dia.2018.0347
147. Kovatchev BP, Renard E, Cobelli C, et al. Feasibility of outpatient fully integrated closed-loop control: first studies of wearable artificial pancreas. *Diabetes Care*. 2013;36(7):1851-1858. doi:10.2337/dc12-1965
148. Nagel KE, Dearth-Wesley T, Herman AN, Smith HG, Whitaker RC. Diabetes distress and glycaemic control in young adults with type 1 diabetes: associations by use of insulin pumps and continuous glucose monitors. *Diabet Med*. 2021;38(11):e14660. doi:10.1111/dme.14660
149. Vesco AT, Jedraszko AM, Garza KP, Weissberg-Benchell J. Continuous glucose monitoring associated with less diabetes-specific emotional distress and lower A1c among adolescents with type 1 diabetes. *J Diabetes Sci Technol*. 2018;12(4):792-799. doi:10.1177/1932296818766381
150. Prahalad P, Addala A, Scheinker D, Hood KK, Maahs DM. CGM initiation soon after type 1 diabetes diagnosis results in sustained CGM use and wear time. *Diabetes Care*. 2020;43(1):e3-e4. doi:10.2337/dc19-1205
151. Wang CH, Hilliard ME, Carreon SA, et al. Predictors of mood, diabetes-specific and COVID-19-specific experiences among parents of early school-age children with type 1 diabetes during initial months of the COVID-19 pandemic. *Pediatr Diabetes*. 2021;22(7):1071-1080. doi:10.1111/pedi.13255
152. Markowitz JT, Pratt K, Aggarwal J, Volkening LK, Laffel LM. Psychosocial correlates of continuous glucose monitoring use in youth and adults with type 1 diabetes and parents of youth. *Diabetes Technol Ther*. 2012;14(6):523-526. doi:10.1089/dia.2011.0201
153. Patton SR, Clements MA. Psychological reactions associated with continuous glucose monitoring in youth. *J Diabetes Sci Technol*. 2016;10(3):656-661. doi:10.1177/1932296816638109
154. Tanenbaum ML, Hanes SJ, Miller KM, Naranjo D, Bensen R, Hood KK. Diabetes device use in adults with type 1 diabetes: barriers to uptake and potential intervention targets. *Diabetes Care*. 2017;40(2):181-187. doi:10.2337/dc16-1536

155. Addala A, Suttiratana SC, Wong JJ, et al. Cost considerations for adoption of diabetes technology are pervasive: a qualitative study of persons living with type 1 diabetes and their families. *Diabet Med*. 2021;38(10):e14575. doi:10.1111/dme.14575
156. Naranjo D, Suttiratana SC, Iturralde E, et al. What end users and stakeholders want from automated insulin delivery systems. *Diabetes Care*. 2017;40(11):1453-1461. doi:10.2337/dc17-0400
157. de Bock MI, Roy A, Cooper MN, et al. Feasibility of outpatient 24-hour closed-loop insulin delivery. *Diabetes Care*. 2015;38(11):e186-e187.
158. Haidar A, Rabasa-Lhoret R, Legault L, et al. Single- and dual-hormone artificial pancreas for overnight glucose control in type 1 diabetes. *J Clin Endocrinol Metab*. 2016;101(1):214-223. doi:10.1210/jc.2015-3003
159. Sharifi A, De Bock MI, Jayawardene D, et al. Glycemia, treatment satisfaction, cognition, and sleep quality in adults and adolescents with type 1 diabetes when using a closed-loop system overnight versus sensor-augmented pump with low-glucose suspend function: a randomized crossover study. *Diabetes Technol Ther*. 2016;18(12):772-783. doi:10.1089/dia.2016.0288
160. Hovorka R, Elleri D, Thabit H, et al. Overnight closed loop insulin delivery in young people with type 1 diabetes: a free-living randomised clinical trial. *Diabetes Care*. 2014;37(5):1204-1211. doi:10.2337/DC13-2644
161. Weissberg-Benchell J, Shapiro JB, Hood K, et al. Assessing patient-reported outcomes for automated insulin delivery systems: the psychometric properties of the INSPIRE measures. *Diabet Med*. 2019;36(5):644-652. doi:10.1111/dme.13930
162. Battelino T, Danne T, Bergenstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. *Diabetes Care*. 2019;42(8):1593-1603. doi:10.2337/dci19-0028

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